

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Update to the List of Medical Supplies

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice, publication of updated list of items defined as medical supplies

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing an updated list of items defined as medical supplies under section 560.530(a)(3)(ii) of the Iranian Transactions and Sanctions Regulations, 31 CFR part 560, and generally licensed for exportation or reexportation to Iran pursuant to section 560.530(a)(3)(i), to include additional items.

DATES: Effective Date: November 2, 2015.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202-622-2480, Assistant Director for Regulatory Affairs, tel.: 202-622-4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202-622-2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The text of the List of Medical Supplies and additional information concerning OFAC are available from OFAC's Web site (www.treasury.gov/ofac). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202-622–0077.

Background

On October 22, 2012, OFAC published a final rule in the Federal Register (77 FR 64664) that, among other things, amended section 560.530 of the Iranian Transactions and Sanctions Regulations, 31 CFR part 560 (ITSR), to add a general license, in new paragraph (a)(3), authorizing the exportation or reexportation of medicine and basic medical supplies to Iran. The term "basic medical supplies" was defined to mean those medical devices, as defined in paragraph (e)(3) of section 560.530, that were included on the "List of Basic Medical Supplies" on the OFAC Web site (www.treasury.gov/ofac) on the Iran Sanctions page, but not including replacement parts. On the same day, OFAC also posted the List of Basic Medical Supplies on its Web site (78 FR 54731). OFAC updated the List of Basic Medical Supplies on its Web site (78 FR 54731).

On April 7, 2014, OFAC published a final rule in the Federal Register (79 FR 18990) that, among other things, updated the definition of "basic medical supplies" to exclude the word "basic" and make related conforming changes. Accordingly, the rule further provided that the "List of Basic Medical Supplies" published on the OFAC Web site and in the <u>Federal Register</u> would now be called the "List of Medical Supplies."

As highlighted in the note to paragraph (a)(3)(ii) of section 560.530 of the ITSR, the List of Medical Supplies is maintained on OFAC's Web site and will be published in the <u>Federal</u>

Register, as will any changes to the list. On November 2, 2015, OFAC updated the List of Medical Supplies on its Web site to read as follows:

GENERAL LICENSE 31 CFR 560.530(a)(3)

Authorizing the exportation or reexportation of medicine and medical supplies to Iran

LIST OF MEDICAL SUPPLIES (updated November 2, 2015)

The list below comprises the medical supplies defined in 31 CFR 560.530(a)(3)(ii)

General Medical Equipment and Supplies

- Adhesive designed for human use
- Adhesive remover designed for human use

- Antiseptic wipes for human use (including alcohol, antimicrobial, benzalkonium, betadine, iodine, and witch hazel)
- Beds: hospital beds, cribs, or bassinets; including mattresses, overlays, pillows, and bumpers
- Blood lancets
- Blood pressure monitors, gauges, cuffs, aneroids, or infusors
- Bottles (prescription)
- Cabinets: medical supply or pharmaceutical
- Canes, crutches, walkers, rollators
- Capnographs
- Carts: medical, medical utility, medical supply, food service, or hospital laundry carts
- Catheters all sizes and types; including kits
- Chairs: exam, treatment, surgical, dental, or phlebotomy
- Clinical basins, bowls, baths, pans, urinals, bags, and buckets; and holding devices for such items
- Clinical swabs, applicators, specimen collectors, sponges, pads, tongue depressors, wooden spoons, cotton balls, or cotton rolls
- Coils, guidewire
- Contraceptives (inter-uterine devices (IUDs), hormonal therapy methods, barrier methods), and condoms
- Continuous positive airway pressure (CPAP) systems and all components
- Ear plugs and muffs

- Ear syringes
- Ear wax removers
- Endoscopic devices including laryngoscopes, laparoscopes, anascopes, proctoscopes, arthroscopes, sinuscopes, dematoscopes, ophthalmoscopes, sigmoidscopes, otoscopes, retinoscopes, or colposcopes
- Floor mats: safety, anti-fatigue or special-purpose medical floor mats
- Forceps
- Guidewires, all
- Human body or cadaver bags and shrouds
- Human body positioners including pads, wedges, cradles, pillows, rests, straps, supports,
 and holders
- Human specimen collectors and containers (e.g., urine, blood, tissue)
- Humidifiers
- Hydrocollator heating units
- IV sets, bags, and armboards
- Jars and containers designed for medical supplies and instruments less than 5 L internal volume
- Lights and lamps: surgical, or medical exam, magnifying
- Limb prosthesis devices
- Manikins: medical training, CPR
- Medical bags for medical supplies and equipment; including pre-packed bags
- Medical bandages, gauze, dressings, tape, swabs, sponges, and burn dressings

- Medical carafes, cups, containers and tumblers
- Medical casts, padding; and casting and removal equipment
- Medical defibrillators
- Medical diagnostic kits, point-of-care; including EAR99 reagents
- Medical flowmeters: oxygen & air
- Medical labels, labellers, stickers, forms, charts, signage, tags, cards, tape, wrist bands, documents, brochures, and graphics
- Medical lavage systems
- Medical linens (e.g., blankets, sheets, pillow cases, towels, washcloths, drapes, covers)
- Medical penlights
- Medical pumps
- Medical scissors
- Medical tubing or hoses less than 2" diameter; including associated adaptors, connectors, caps, clamps, retainers, brackets, valves, washers, vents, stopcocks, or flow sensors; and peristaltic pumps with flowrates of less than 600 liters/hr for such tubing (note: does not include tubing made of butyl rubber or greater than 35% fluoropolymers)
- Medicine cups
- Monitor for glucose management
- Non-electronic patient medical record file systems and organizers
- Orthopedic supports, braces, wraps, shoes, boots, or pads
- Orthopedic traction devices and tables
- Otology sponges

- Oxygen apparatus, all
- Paraffin baths
- Patient heating and cooling devices: pads, packs, bottles, bags, warmers, blankets, patches, lamps, bags
- Patient safety devices including vests, aprons, finger mitts, limb or body holders, jackets,
 belts, restraints, cuffs, straps, or protectors
- Patient transfer chairs, lifts, benches, boards, slides, discs, slings, and sheets
- Patient vital-sign monitoring devices
- Patient wheelchairs, chairs, gurneys, stretchers, mats, and cots
- Privacy screens and curtains
- Pulse oximeters
- Reflex hammers
- Refrigerator: compartmental for morgues
- Safety poles, rails, handles, benches, grab bars, commode aids, and shower aids
- Scales, stadiometers, rulers, sticks, tapes, protractors, volumeters, gauges, or callipers designed for human measurement
- Single-use medical procedure trays and kits
- Speculums
- Spirometers
- Splints
- Stands: IV, instrument, solution, or hamper
- Stethoscopes

- Stools: designed for clinical use
- Surgical sutures and staples; and removal kits
- Syringes, aspirators, cannulas, and needles all sizes and types; including kits
- Tables: operating, exam, therapy, overbed, treatment, medical utility, or medical instrument
- Telemetry pouches designed for human use
- Tents: pediatric, aerosol, and mist
- Thermometers for measuring human body temperature
- Tourniquets
- Ventilator: adult and tubing and accessories
- Warmers: bottle, gel, lotion, or blanket

Anaesthesiology

- Air bags and tidal volume bags
- Air bellows
- Anaesthesia circuits
- Anaesthesia machines, vaporizers, nebulizers, and inhalers designed for individual human use
- Anaesthesia masks (including laryngeal)
- Anti-siphon equipment
- Block and epidural trays packaged for individual use

- Endotrach tubes
- Head straps and harnesses
- Hyperinflation systems
- In-line filters and cartridges, thermometers, CO₂ detectors, sodalime canisters, and temperature and moisture exchangers (note: gas mask canisters, other than sodalime canisters designed for anaesthesia systems, require a specific license)
- Intubation sets, probes and related equipment
- Anaesthesiometers
- Oral airways
- Peripheral nerve stimulators
- Anaesthesia pressure tubes and controllers
- Cardiopulmonary resuscitation (CPR) training manikins and lung bags
- Vibration dampening mounts

Apparel

- Medical gowns, scrubs, aprons, uniforms, lab coats, and coveralls; only those without integrated hoods
- Patient clothing including gowns, slippers, underpads, or undergarments
- Head or beard covers and nets
- Medical shoe and boot covers
- Surgical sleeve protectors

Ventilated Safety eyeshields and goggles (does not include full face shield or indirectly-

vented goggles)

- Disposable latex, nitrile, polyethylene, vinyl gloves/finger cots or other medical gloves
- Surgical face or dust masks (does not include masks with respirators)

Cardiology

- Ablation devices and accessories: radio frequency
- Balloons extractor, retrieval
- Cardiac monitors: implantable or external
- Cardiac pacemakers
- Cardiac programmers
- Cardiopulmonary oxygenation systems, devices, and monitors
- Coagulation machines
- Electrocardiography machines
- Filters: arterial
- Grafts: peripheral bypass
- Heart positioners: surgical revascularization
- Heart valves: surgical transcatheter (non-surgical)
- Inflation devices: interventional

Dental equipment and supplies

- Bone graft matrices
- Dental and oral implants or devices
- Dental instrument cases, trays, mats or tray liners, racks, covers, wraps, stands, holders, stringers, or protectors
- Dental instruments all types and sizes
- Denture and temporary oral device containers
- Dentures, crowns, molds, orthodontics, all
- Tooth and denture brushes
- Yankauers

Gynecology & Urology

- Bladder control pads, briefs, liners, underwear, pants and diapers
- Bladder scanners
- Enema sets
- Extracorporeal lithotripters
- Fecal/stool management devices, kits, and catheters
- Feminine hygiene products
- Pouches, urostomy

Inherited Preventative Care

• Genetic testing products

Laboratory

- Autoclaves (20 liters or smaller only) for medical instrument sterilization and accessories
- Automated blood culture systems
- Automated clinical chemistry analyzers for patient care
- Bench-top dry bath incubators
- Clinical immunoassay analyzers
- Clinical laboratory water baths less than 10 liter
- Coagulation analyzers
- Co-oximeters for haemoglobin analysis
- Electrolyte analyzers
- Flow cytometry accessories, reagents, and components
- Hematology analyzers
- Histology and cytology strainers and tissue baths
- Laboratory balances and scales not to exceed 10 Kg
- Laboratory hot plates with less than 1.0 sq. ft. heating surface
- Laboratory pH meter (with or without temperature probe)
- Light microscopes
- Luminometers
- Medical bone densitometers

- Medical differential counters
- Medical refrigerators and freezers with less than 5.0 cu. ft. internal volume
- Medical specimen centrifuges
- Microplate readers/washers
- Osmometers
- Patient blood gas analyzers
- Pipettes
- Spectrophotometers, photometers, and colorimeters designed for clinical use
- Urinalysis analyzers

Nephrology

- Hemodialysis machines; and dialysis filters designed for such machines (Note: Other dialysis equipment, filters, and parts not used for hemodialysis require a specific license and may be controlled under 15 CFR, part. 774, supp. 1, ECCN 2B352.d)
- Hemodialysis connection or tubing kits

Neurology

- Electroencephalography machines
- Neurostimulators, implantable

Obstetrics and Maternity Care

- Assisted reproductive technology and related equipment
- Incubators/Isolettes
- Infant radiant warmer and parts and accessories
- Neonatal equipment (phototherapy, nasal CPAP, etc. and all components)
- Umbilical cord clamps
- Ventilator: infant/pediatric and tubing and accessories

Ophthalmology and Optometry

- Contact Lens cleaning solutions
- Contact Lenses, corrective
- Eyecharts
- Glasses, corrective
- Phoropters
- Tonomets
- Vision/Optometry related machines and supplies

Otology and Neurotology

• Hearing aids, accessories, and components

Physical and Occupational Therapy

- Aquatic floats and training devices
- Balance pads, platforms, and beams
- Bath cubes, therapy
- Boots, mitts, and liners for therapeutic pain relief
- Cognitive measuring devices and equipment
- Dining aids
- Electrotherapy, muscle stimulators, and tens units
- Ergometers
- Exercise bars
- Exercise table
- Fine motor assessment equipment designed for human use
- Goniometers
- Hand bars
- Hydraulic dynamometer
- Manipulation boards
- Massaging equipment
- Mat Platforms
- Medical Whirlpools
- Mobility platforms, parallel bars, ladders, stairs
- Orthopedic shoes, boots, etc.

- Parallel bars
- Pedometers
- Protective headgear
- Rehabilitation exercise, weights, band, balls, boards, and mobility equipment
- Rulonmeters
- Scoliometer
- Tactile sensation, sensitization, and desensitization equipment
- Therapeutic putty
- Ultrasound stimulators

Radiology

- Computer tomography scanners (CT, MDCT)
- Contrasting agents, both injectable or non-injectable
- Magnetic resonance imaging (MRI) machines
- Medical ultrasound machines
- Medical/Dental film
- Nuclear medicine imaging machines
- Positron Emission Tomography (PET)
- PET cyclotron machines
- PET radiopharmaceutical tracer machines, including cassettes
- Scintillation Camera/Anger cameras for medical imaging

- Single Photon Emission Computed Tomography (SPECT) machines
- X-ray machines, including mammography machines
- Parts and accessories for medical imaging devices above that do not contain nuclear or chemical components

Sterilization

- Aseptic, germicidal, or disinfectant wipes or clothes for medical equipment, devices or furniture
- Ready-to-use disinfectant in 32 oz. containers or less
- Aseptic, germicidal, or medical-grade soap, detergent, pre-soak, or rinse in 1 gallon containers or less
- Hand sanitizer, lotion, soap, scrub, wash, gel, or foam; including dispensing devices
- Medical cleaning brushes for equipment, patients, and furniture
- Sterilization or disinfection indicator strips, tape, or test packs
- Medical instrument sterilization pouches, mats, protector guards, or tubing
- Sterilization containers or cases less than 0.3 cu. ft.
- Autoclaves with chamber size less than 0.3 cu. ft.; including trays, containers, cassettes,
 cases, and filters for such systems.

Surgery

- Blood transfusion equipment
- Cervical fusion kits
- Chest drains
- Cosmetic or reconstructive implants (jaw implants, breast implants, skin grafts
- Electrosurgery devices and supporting equipment
- Lubricant specially-formulated for surgical equipment in 1 gallon containers or less
- Orthopedic plates/screws, fixators, implants, cement
- Stents all types and sizes
- Stockinettes
- Surgical case carts
- Surgical clean-up kits
- Surgical clips
- Surgical imaging machines; including image-guiding surgery products, ear, nose and throat
- Surgical instrument cases, trays, mats or tray liners, racks, covers, wraps, stands, holders, stringers, or protectors
- Surgical instruments all types and sizes
- Surgical linens, drapes, or covers
- Surgical mesh
- Surgical shunts
- Surgical smoke evacuators and specialized supporting equipment
- Tissue stabilizers, surgical revascularizations

• Wound drainage equipment

EAR99-classifed components, accessories, and optional equipment that are designed

for and are for use with an EAR99-classified medical device included elsewhere on the list.

With this notice, OFAC is publishing the updated list of items defined as medical

supplies in the Federal Register.

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